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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,933	04/15/2004	James R. Braig	OPTIS.100A	7558

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EXAMINER

AKANBI, ISIAKA O

ART UNIT	PAPER NUMBER
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2886

NOTIFICATION DATE	DELIVERY MODE
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07/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/824,933	Applicant(s) BRAIG ET AL.	
	Examiner ISIAKA O. AKANBI	Art Unit 2886	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 24, 31-37, 40-44 and 46-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 24, 31-37, 40-44 and 46-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

The amendment filed on 09 April 2008 has been entered into this application. Claims 21-23, 25-30, 38-39, and 45 are cancelled. Claims 49-51 have been added.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20, 24, 31-37, 40-44, and 46-51 are rejected under 35 U.S.C. 102 (b) as being anticipated by Allen et al. (EP0397424 A2).

As regard to claims 1, 2, 3, 4 and 46, Allen discloses a reagentless sample element comprising of the following:

first and second (**fig. 1: 20, 24, 24, 41, 48, 60, 62, 64, and 66**) substantially parallel faces, the parallel faces at least partially defining a sample chamber configured to hold a volume of fluid, the sample chamber being reagentless (**page 10, lines 34- page 11, line 3**);

an optical path extending through the parallel faces and the sample chamber **(fig. 4: 212/214 and 222/224)**, such that electromagnetic radiation can propagate through the sample chamber **(page 11, lines 34-42)**; and

an optical key for qualifying the sample element for use with a particular analyte detection system **(page 11, lines 33-36)**, the optical key comprising:

an identifying compound disposed within or on at least one of the parallel faces of the sample chamber, the sample element configured such that the identifying compound does not intermingle with the sample fluid, the identifying compound also disposed in the optical path such that the electromagnetic radiation passes through **(transmissive)** the identifying compound as the radiation propagates through the sample chamber **(fig. 4)(page 10, lines 34-page 11, line 3)**;

at least a portion of a spectral scan of the identifying compound stored in the analyte detection system **(computer memory)(fig. 4: 200)**;

the identifying compound having at least one indexed optical absorbance feature, such that the spectral scan generated by electromagnetic radiation propagated through the parallel face having the identifying compound therein or thereon yields the indexed **optical absorbance** feature **(page 12, lines 2-3)(page 9, lines 3-4 and lines 16-17)**.

As to claims 5 and 6, Allen also discloses wherein the analyte detectable by the analyte detection system is glucose and the indexed optical absorbance feature is an absorbance maximum or an absorbance minimum **(page 4, lines 56-57 and page 5, lines 8-14)(page 12, lines 2-3)**.

As to claim 7, Allen also discloses identifying compound is a hydrocarbon (**pages 4-5**).

As to claim 8, Allen further discloses the limitation wherein the identifying compound is a coating (**reagents used in the for example ALT analysis**) on at least a portion of the sample element (**page 10, lines 45-49**).

Regarding to claims 9, 14-17, 31-33, 40, 42-44, 47 and 48, Allen discloses a sample element that is verifiable as approved for use with a detection system comprising:

an optical path (**fig. 4: 212/214 and 222/224**) for determining analyte concentration (**page 11, lines 34-42**); and

an identification key in the optical path for verifying (**fig. 4: 220**) that the sample element (**page 11, lines 33-36**), is approved (i.e. by having appropriate detection means), the identification key comprising an optical property (**reagents used in the for example ALT analysis**) of the sample element (**page 10, lines 45-49**);

receiving (**fig. 3A-C: 110**)(**page 11, lines 14-27**) the sample element (**fig. 4: 10**) in an analyte detection system (**fig. 4: 210**); after receiving, emitting radiation along an optical path (**fig. 4: 212/214 and 222/224**), the optical path for optically determining analyte concentration; wherein emitting radiation results in **an absorption spectrum** (**page 12, lines 2-3**);

qualifying the sample element (**fig. 4: 10**) by optically determining whether the sample element is of a type which is suitable for use with the analyte detection system,

if the sample element is of a type which is suitable for use with the analyte detection system, analyzing an optical property of the material sample; and if the sample element is not of a type which is suitable for use with the analyte detection system, refusing to analyze an optical property of the material sample **(page 11, lines 34-46)**.

As to claim 10, Allen also discloses wherein the optical property is an optical absorption of a window in the optical path **(fig. 4: 212/214, 222/224 and 232/234)(page 9, lines 16-17)(page 12, lines 2-3)**.

As to claims 11, 12 and 13, Allen also discloses sample element that is characterized by optical property that is a thickness of a window in the optical path; wherein the optical property is a thickness of sample chamber in the optical path; and wherein the optical property corresponds to a background optical absorbance spectrum of the optical path **(fig. 4: 212/214, 222/224 and 232/234)(page 9, lines 16-17)(page 12, lines 2-3)**.

As to claims 18 and 19, Allen also discloses wherein the analyte detectable by the analyte detection system is glucose and the indexed optical absorbance feature is an absorbance maximum or an absorbance minimum **(page 4, lines 56-57 and page 5, lines 8-14)(page 12, lines 2-3)**.

As to claim 20, Allen also discloses identifying compound is a hydrocarbon **(pages 4-5)**.

As to claim 24, Allen also discloses the limitation wherein the identification key **(reagents used in the for example ALT analysis)** comprises an identification medium within or applied on the sample element **(page 10, lines 45-48)**.

As to claims 34, 35 and 36, Allen also discloses wherein qualifying the sample element comprising measuring an optical absorbance spectrum of the sample element and analyzing the measured optical absorbance spectrum for a qualifying absorbance feature (i.e. by being absorbance maximum or an absorbance minimum) and reading at least one datum from an identification medium (sample) **(page 4, lines 56-57 and page 5, lines 8-14)(page 12, lines 2-3).**

As to claim 37, Allen also discloses wherein qualifying the sample element further comprising checking whether the datum corresponds to a datum stored in the analyte detection system **(pages 12 and 13: table 1 and 2).**

As to claim 41, Allen also discloses a reagentless sample chamber **(fig. 1: 24 and 48)** in said optical path **(page 10, lines 42-45 and lines 51-52).**

As to claim 49, Allen also discloses a transmissive structure **(fig. 1: 20, 28)** disposed adjacent the reagentless sample chamber **(fig. 1: 24 and 48) (page 10, lines 42-45 and lines 51-52).**

As to claim 50, Allen further discloses transmissive structure that is a hydrocarbon **(pages 4-5).**

As to claim 51, Allen also discloses the limitation wherein emitting radiation along an optical path through (transmissive) the sample element comprises emitting radiation through a window doped with a hydrocarbon **(i.e. reagents used in the for example ALT analysis)(page 10, lines 45-48).**

Additional Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references listed in the attached form PTO-892 teach of other prior art sample element.

Response to Arguments

Applicant's arguments with respect to claims 1-20, 24, 31-37, 40-44, and 46-48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isiaka Akanbi whose telephone number is (571) 272-8658. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tarifur R. Chowdhury can be reached on (571) 272-2287. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isiaka Akanbi

July 10, 2008

/TARIFUR R CHOWDHURY/
Supervisory Patent Examiner, Art Unit 2886